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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,904	08/22/2003	Herbert Irschik	103832-510-NP	1332

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EXAMINER	
QAZI, SABIHA NAIM	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
05/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/646,904	IRSCHIK ET AL.	
	Examiner	Art Unit	
	Sabiha Qazi	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,9-14 and 18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-3 and 14* is/are allowed.

6)☐ Claim(s) *4, 5, 9-13 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Final Office Action

Claims 1–5, 9-14 and 18 are pending. Amendments are entered.

Summary of this Office Action dated 4/27/2008

1. 35 USC § 112 --- First Paragraph Written Description Rejection

2. Response to Remarks

3. Communication

35 USC § 112 --- First Paragraph Written Description Rejection

1. Claims 4–5, 9-13 and 18 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Following reasons apply.

Applicants Claims:

A method for the treatment of oncoses selected from the group consisting of tumors of the lung, the breast, the stomach, the neck, the uterus, the prostate, the head and neck, the large and small intestinal and the liver and the blood system; ovarian carcinoma, prostate carcinoma; glioblastoma; lung carcinomal breast cancer; skin cancer; colonic cancer; renal cell cancer; hepatic cancer; pancreatic cancer;, cervical cancer; and cancers of the brain, comprising administering a compound of the disorazole compound of general formula la alone or in combination with a cytotoxic substance and/or an inhibitor of signal transduction to an individual in need thereof of such treatment (claim 4) and a method of inhibiting mitosis in rapidly and uncontrollably proliferating endogenous cells in humans or animals (claim 5).

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See, e.g., In re Wilder, 22 USPQ 369, 372-3 (Fed. Cir. 1984). (Holding that a claim was not adequately described because the specification did 'little more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.')

Mere indistinct terms (such as method claims as presented), however, may not suffice to meet the written description requirement. This is particularly true when a compound is claimed in purely functional terms. See Univ. of Rochester v. G.D. Searle, 69 USPQ2d 1886 (CAFC 2004) at 1892, stating:

> The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice…. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. (Emphasis added).

Conversely, a description of a chemical genus will usually comprise a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. See Univ. of Calf. V. Eli Lilly, 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997). This is analogous to enablement of a genus under Section 112, ¶ 1, by showing the enablement of a representative number of species within the genus.

A chemical genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. If the genus has substantial variance, the disclosure must describe a sufficient number of species to reflect the variation within that genus. See MPEP 2163. The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. MPEP 2163.

Furthermore, the written description requirement prevents applications from using the amendment process to update the disclosure in their disclosures (claims or specification) during the pendency before the patent office. Otherwise applicants could add new matter to their disclosures and date them back to their original filing date, thus defeating an accurate accounting of the priority of the invention. See 35 USC 132. The function of description requirement is to ensure that the inventor had possession, as of filing date of the application relied on, the specific subject matter claimed by him.

See *Genetech,* 108 F 3d 1361, 1365 (Fed. Cir. at 1366, 78, 1999).

In the present case Applicant has no possession of the subject matter of claim 1 and its dependent claims including the for method of treatment of oncoses, uncontrolled proliferation, sarcoma, acute lymphatic leukemia (ALL) acute promyleotic leukemia (APL) Hodgkin's disease, lung carcinoma and many more by disorazole compounds of formula I as in claim 1. The specification provides test data for proliferation of three disorazole compounds A1, D1 and E1, the claims are too broad and disclosure does not provide guidance or direction for the treatment of all the diseases as claimed. Applicant has no possession of the claimed subject matter at the time the invention was made.

Table 1 on page 16 discloses the inhibition of proliferation by Disorazole E1, D1 and A1 according to the invention in the XTT cytotoxicity test on human cell lines (proliferation assay, EC50 in □g/ml). Tables 2-4 and comparison with the reference compounds has been fully

considered. There is no example to use the compound with another "antitumor agent" or signal transduction inhibitors".

See In re Buting, 163 USPQ 689. The disclosure provides no indication of whether the compounds treat all cancers. To make clearer the lack of enablement for treatment of all cancer, extrinsic evidence is supplied by Draetta (Ann. Reports Med. Chem.), Draetta et al. in "Annual Reports in Medicinal Chemistry"., 1996, Academic Press, San Diego, pp 241-246, final sentence on page 246 although many still think about the need for a magic bullet as a cure for all cancers, our knowledge of the molecular mechanism underlying this disease make the prospect of developing such a universal cure very unlikely." Since no universal cure for cancer has been developed, it follows that there is no correlation between the assays relied upon by applicants and the ability to treat all types of diseases base on rapid and uncontrolled proliferation of endogenous cells. Thus, the data as presented are not sufficient to enable such claims.

Further, in the art of clinical oncology, no compound has yet shown clinical efficacy against every type of cancer. Different agents are used for different forms of cancer and no single agent is listed as a treatment of every single type of cancer. Balasubramanian reference (Recent Developments in Cancer Cytotoxics) on page 151 first paragraph "the successful treatment of solid tumors remains a formidable challenge." There is no teaching as to how the claimed compound(s) for the "treatment of a disease in humans or animals which is based on rapid and uncontrolled proliferation of endogeneous cells comprising administering the compound of claim 1 to a human or animal in need of such a treatment". (claim 5). The treatment of oncoses, uncontrolled proliferation, sarcoma, acute lymphatic leukemia (ALL) acute promyleotic leukemia (APL) Hodgkin's disease, lung carcinoma and many more by disorazole

compounds of formula I as in claim 1 is not predictable. The specification provides test data for proliferation of three disorazole compounds A1, D1 and E1, since there is no guidance and/or direction provided by the Applicants for method of treatment of oncoses, uncontrolled proliferation, sarcoma, acute lymphatic leukemia (ALL) acute promyleotic leukemia (APL) Hodgkin's disease, lung carcinoma and many more by disorazole compounds of formula I as in claim 1 one skilled in the art would not be able to make and use the invention.

The specification provides test data for proliferation of three disorazole compounds A1, D1 and E1, the claims are too broad and disclosure does not provide guidance or direction for the treatment of all the diseases as claimed. See MPEP 2163.06.

The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to one skilled in the art that the inventor had the possession at the time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claimed language. See In re Kaslow, 707 F 2d 1366, 1375 (Fed. Cir. 1983).

Claims 1-3 and 14 are allowed.

Response to Remarks

A proviso in the definition of X and Y has been noted. Applicant is requested to disclose the disclaimed prior art.

Applicant's arguments are fully considered but are not found persuasive therefore written description is maintained. The data in specification does not commensurate with the scope of claims. The specification provides test data for proliferation of three disorazole

compounds A1, D1 and E1, since there is no guidance and/or direction provided by the Applicants for method of treatment of oncoses, uncontrolled proliferation, sarcoma, acute lymphatic leukemia (ALL) acute promyleotic leukemia (APL) Hodgkin's disease, lung carcinoma and many more by disorazole compounds of formula I as in claim 1 one skilled in the art would not be able to make and use the invention.

The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to one skilled in the art that the inventor had the possession at the time of the later claimed subject matter, rather than the **presence or absence of literal support in the specification for the claimed language**. See In re Kaslow, 707 F 2d 1366, 1375 (Fed. Cir. 1983).

Conclusion

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day except Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sabiha Qazi/
Primary Examiner, Art Unit 1612